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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,842	05/16/2006	Wai Ming Wong	P001.006NPEUS	7752

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EAGLE IP LIMITED
22/F., KWAI HUNG HOLDINGS CENTRE
89 KING'S ROAD
NORTH POINT,
HONG KONG

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,842	WONG ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070213*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

A computer readable form of the sequence listing was filed on May 16, 2006 and was approved by STIC. However, the examiner can not locate any paper copy of the Sequence Listing in the Image File Wrapper, nor can he locate any statements required under 37 CFR 1.821(f).

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b). Applicants can omit submission of a substitute CRF as long as the statements are modified to refer specifically to the CRF filed May 16, 2006.

2. The substitute specification filed July 12, 2007 is approved for entry.

3. The Listing of Claims submitted in the preliminary amendment filed July 12, 2007 does not comply with 37 CFR 1.121(c) because the claim listing does not include status identifiers within parentheses for each of the listed claims. Any future amendments should be carefully checked for compliance with the amendment rules.

4. The abstract of the disclosure is objected to because more detail as to the particular pharmaceutical uses contemplated by Applicants is necessary. Further, a SEQ ID NO must be

inserted after the amino acid sequence recited in the abstract. See 37 CFR 1.821(d). Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: A SEQ ID NO must be inserted after each amino acid sequence recited in the specification which is subject to the sequence disclosure rules. See 37 CFR 1.821(d). At page 35, line 7, the patent number is incorrect (compare the patent number at line 13), and the inventor name is misspelled. Appropriate correction is required.

6. The amendment filed July 12, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The incorporation by reference to the provisional application inserted into the first paragraph of the specification is new matter, because the incorporation by reference statement was not present in the application as originally filed. See MPEP 201.11(III), first paragraph, and (III)(F), last paragraph.

Applicant is required to cancel the new matter in the reply to this Office Action.

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "use" is not a statutory class of invention.

8. Claims 2-4 and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of "consisting essentially of" at claim 2, line 1,

is not clear. Applicants give two alternative and not necessarily consistent definitions of the term at pages 13-14 of the specification, one based upon the primary activity of the peptide, and one based upon the number of amino acids which may be added to the termini of LVTNTT. It is not clear which of these definitions controls, or if both must be satisfied in order to meet the limitations of the claim. Also, with respect to the definition of "consisting essentially of" based upon the primary activity of the peptide, it is not clear what constitutes a "primary activity" of a given peptide. A "primary activity" is not intrinsic to a compound, but is dependent upon, e.g., who is testing or using the peptide, and the point in time at which the primary activity is determined (because the uses of a peptide can change with time). Determination of the claim scope without specifying at least these variables is not possible. It is not clear what constitutes a "use" as is recited in instant claims 15-19. It is not clear if Applicants are claiming, e.g., a method of use, or a product with an intended use limitation. To the extent that Applicants are claiming a method of use, the claims are indefinite because they are drawn to a method of use, but no positive process steps are recited in the claims.

9. Claims 1-20 are objected to because of the following informalities: SEQ ID NOS must be inserted after every occurrence of an amino acid sequence subject to the sequence disclosure rules which appears in the claims. See 37 CFR 1.821(d). Appropriate correction is required.

10. Applicant is advised that should claim 8 be found allowable, claim 9 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a

substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 8 and 9 appear to be identical in scope.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by the Vassilev et al article (Hepato-Gastroenterology, Vol. 43, pages 882-886) in view of Applicants admission of the prior art in the paragraph bridging pages 10-11 of the specification. The Vassilev et al article teaches Polyerga, a fraction of low molecular weight glycoproteins isolated from animal spleen. The fraction is administered to patients with chronic hepatitis B infections, probably by increasing lymphokine secretion and generation of cytotoxic T-cells. The fraction is administered intramuscularly and in tablet form. See, e.g., the Abstract. Applicants admit in the paragraph bridging pages 10-11 of the specification that the peptide IVTNTT was obtained from the same fraction taught by the Vassilev et al article. Accordingly, the fraction of the Vassilev et al article inherently comprises IVTNTT. Because the Vassilev et al article teaches its fraction to have been "isolated" from animal spleen, and because the Vassilev et al article teaches its fraction to have the same activity recited in Applicants' claims, the isolated fraction of the Vassilev et al article meets Applicants' claim requirements for an "isolated or purified" peptide and for a peptide in a "substantially pure form". Note that the claims do not specify to what degree the peptide must be isolated or purified, or from what the peptide must be isolated or purified. The terms "isolated" and "purified" are not defined in Applicants' specification so as to

distinguish over the peptide which is present in the isolated fraction taught by the Vassilev et al article. Note also that instant claims 8-20 do not require that peptide to be in isolated or purified form. With respect to instant claim 20, the non-peptidic components of the tablet of the Vassilev et al article correspond to Applicants' enhancement molecules which enhance the therapeutic effectiveness of the peptide. Note that Applicants define "operably linked" at page 4, lines 7-8, of the specification to include non-covalent interactions between the enhancement molecule and the peptide. Note also that the non-peptidic components of the tablet of the Vassilev et al article, i.e. the pharmaceutically acceptable carrier components, enhance the therapeutic effectiveness of the peptide by permitting easier administration and targeting to the intended organs of the active agents of the fraction.

13. Claims 1-5, 7-11, and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 01/75067. The WO Patent Application '067 teaches an isolated polypeptide comprising SEQ ID NO:33625, and teaches the isolated polypeptide combined with a pharmaceutically acceptable carrier and administered therapeutically to a mammalian subject. See, e.g., claims 20 and 27. SEQ ID NO:33625 of the WO Patent Application '067 is an 81-amino acid residue-containing peptide, having the residues IVTNTT at positions 20-25. In view of the similarity in structure between the peptide of the WO Patent Application '067 and Applicants' claimed peptide, inherently the peptide of the WO Patent Application '067 will be capable of reducing the symptoms of a viral disease such as hepatitis B infection, and inherently the peptide of the WO Patent Application '067 will have immunostimulating properties, to the same extent claimed by Applicants. Because the same active agent is being administered to the subject according to the same method steps, inherently the immune system of the subject will be

stimulated in the method of the WO Patent Application '067 to the same extent claimed by Applicants. Sufficient evidence of similarity is present between the product and method of the WO Patent Application '067 and Applicants' claimed products and methods to shift the burden to Applicants to provide evidence that the claimed products and methods are unobviously different than the product and method of the WO Patent Application '067. With respect to instant claims 15-19, note that an intended use limitation does not impart patentability to a product claim where the product is otherwise anticipated by the prior art. With respect to instant claim 20, the additional amino acids which are present in the peptide of the WO Patent Application '067 correspond to Applicants' enhancement molecule operably linked to IVTNTT. Note that Applicants define "enhancement molecule" at page 4, last paragraph, to include amino acids, peptides, and proteins.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
November 5, 2007